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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
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In re Application of	:
VAN DER BRUGGEN et al	:
Serial No.: 09/782,745	: Decision on Petition
Filing Date: 13 FEBRUARY 2001	:
Attorney Docket No. 7125	:

This letter is in response to the Petition filed under 37 CFR 1.144, to withdraw the restriction requirement, filed with a certificate of mailing date of 16 May 2003. The petition has only recently reached the deciding official and delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application was filed on 13 February 2001 under 35 USC 111(a). A Preliminary Amendment canceled original claims 1-22 and added claims 23-31, directed to nucleic acid molecules, isolated cells, expression vectors and kits. The independent claim is reproduced below:

> 23. An isolated nucleic acid molecule which encodes a GAGE tumor rejection antigen precursor, the amino acid sequence of which is set forth in SEQ ID No: 27, 28, 29, 30 or 31.

In Paper No. 11, mailed 1 May 2002, the Office restricted claims 23-31 into 5 patentably distinct groups, as summarized below:

Group I, Claims 32-40, in part, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor precursor antigen, the amino acid sequence of which is set forth in SEQ ID No. 27.

Group II, Claims 32-40, in part, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor precursor antigen, the amino acid sequence of which is set forth in SEQ ID No. 28.

Group III, Claims 32-40, in part, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor precursor antigen, the amino acid sequence of which is set forth in SEQ ID No. 29.

Group IV, Claims 32-40, in part, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor precursor antigen, the amino acid sequence of which is set forth in SEQ ID No. 30.

Group V, Claims 32-40, in part, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor precursor antigen, the amino acid sequence of which is set forth in SEQ ID No. 31.

Each Group, also containing kits, host cells and expression vectors, was classified in Class 536, subclass 23.5, and Class 435, subclasses 252.3, 320.1 and 975.

The Office reasoned that Inventions I, II, III, IV and V were different products, distinct because their structure was different and they may derive from different genes, which requires non-coextensive searches.

The restriction requirement also included a species election between a type of HLA molecule, review of which was not requested in this petition decision.

Applicant elected Group I, the nucleic acid molecule encoding GAGE-2, which is amino acid sequence set forth in SEQ ID No 27 and encoded by SEQ ID No. 14, with traverse. Applicants argued

> ...that GAGE-2 through 6 are closely related. Note, e.g, figures 4 and 5. Classification for each sequence is precisely the same. The examiner alleges that non-co-extensive searches would be required, but provides no evidence to support this.

In Paper No. 13, mailed 9 August 2002, the examiner considered the arguments but deemed them not to be persuasive as follows:

> The isolated nucleic acid molecules encoding GAGE-2 through GAGE-6 are different nucleic acid molecules and entail separate searches in the nucleic acid databases. The restriction requirement was made final.

Claims 32-40 were examined to the extent that they read upon GAGE-2. Claim 32 was objected to for being dependent upon a rejected base claim. Claims 32 and 33-40 were rejected under 35 USC 112, first paragraph for new matter, because "the specification does not support an isolated nucleic acid molecule which is not one of SEQ ID NO 14, 15, 16, 17 or 18." SEQ ID No. 14 and 27 were considered free of the prior art.

Applicants responded by canceling claims 32-40 and adding new claims 41-51.

Independent claim 41 is reproduced below:

> 41. An isolated nucleic acid molecule which encodes a GAGE tumor rejection antigen precursor, the nucleotide sequence of which is set forth in SEQ ID No: 14, 15, 16, 17 or 18.

This petition was then filed.

DISCUSSION

The application, file history and petition have been considered carefully.

The petition states that the examiner held the claims not reciting specific nucleotide sequences to be non-enabled. To clarify the record, these claims were rejected under 35 USC 112, first paragraph, for lack of written description and for new matter.

The petition argues that only 5 sequences are claimed. The petition argues that there is an extremely high degree of identity amongst SEQ ID Nos. 15-18, as figures 4A-4B show. It is noted that SEQ ID Nos. 15-18 correspond to non-elected Groups II-IV, respectively, and do not include the group under examination. The petition also states that the amino acid sequences of the proteins encoded by these nucleotide sequences do not show exceptional differences.

The petition cites MPEP 803.04, providing part in support of the argument:

> Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together. In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten.

Applicants argue that only 5 sequences are claimed and these five SEQ ID Nos. 15-18 share an extremely high degree of identity, as shown in Figures 4A and 4B. While this is correct, since the publication of the Official Gazette Notice in 1996, the DNA and protein databases have grown in size, exponentially. This has had a direct impact upon the USPTO's searching capability. What was once a relative simple search has now become far more burdensome, due both to performing the computer search and the analysis of the search results. The Official Gazette Notice issued back in 1996 was permissive and not a directive. The Notice stated that up to ten sequences may be allowed. One sequence falls within that range of up to ten sequences.

Applicant is correct that all the Groups fall into the same Class and subclass. However, classification is merely one indication of the burdensome nature of the search involved. The sequence search and literature search, both particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Moreover, a search of SEQ ID No. 14 would not necessarily identify prior art relevant to the examination of SEQ ID No. 15. Further, it is doubted that applicants would readily accept rejection of SEQ ID No. 15 in view of prior art which reads upon SEQ ID No. 14. Clearly different searches and issues are involved in the examination of each group. Thus the searches are not coextensive and search of more than one sequence would be burdensome.

The MPEP clearly states that

> By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

The claims set forth a group of molecules in the alternative. No linking claim or genus type claim is present that would result in linking claims situation, MPEP 809.03.

The petition filed 16 May 2003 has been considered carefully. Figures 4 and 5 of the specification show a high degree of identity between the various sequences, however this is not evidence that the sequences are not independent and distinct inventions. Absent a

statement from applicant, which clearly sets forth that SEQ ID Nos. 14, 15, 16, 17 and 18 are not patentably distinct, one from another, these inventions will be considered as patentably distinct.

DECISION

The petition is **DENIED** for the reasons set forth above.

Any request for reconsideration of this decision must be made by a renewed petition and must be filed within **TWO MONTHS** of the mailing date of this decision in order to be considered timely.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA, 22313-1450 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 308-7230.

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